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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/465,596	06/05/1995	RICHARD F. SELDEN	04270.0015	2132

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EXAMINER	
CROUCH, DEBORAH	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/465,596	SELDEN, RICHARD F.	
	Examiner	Art Unit	
	Deborah Crouch, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72-78,82-84 and 104-108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72-78,82-84 and 104-108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 June 1995* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's arguments filed August 14, 2003 have been fully considered but they are not persuasive. The amendment has been entered. Pending claims are 72-78, 82-84 and 104-108.

The obviousness-type double patenting rejection made in the previous office action of claims 72-78, 82-84 and 104-108 over the claims in application serial no. 08/460,902 has been overcome by applicant's abandonment of the application.

Applicant in the response filed August 14, 2003 argued that based on procedural delay that two-way obviousness-type double patenting should be applied. The issue of procedural delay will not be addressed as two-way obviousness-type double patenting rejections were made in the previous office action.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 72-78, 82-84 and 104-10891-97, 99, 101-103 and 129-134 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 91-97, 99, 101-103 and 129-134 of copending Application No. 08/461,292 for reasons presented in the office action mailed February 11, 2003.

Applicant has stated in the response of August 14, 2003 that a terminal disclaimer will be filed.

Claims 72-78, 82-84 and 104-108 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 135-148 of copending Application No. 09/549,200. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the elements contained in present claims 72-78, 82-84 and 104-108 are contained within the elements of claims 135-148 of '200.

Present claims 72-78, 82-84 and 104-108 are drawn to a method of transferring a gene into a recipient subject comprising transfecting somatic cells in vitro with a DNA sequence, screening transfected cells to select a cells that is stably transfected with the DNA sequence, cloning and expanding the selected cell in vitro and injected the resulting cell into the recipient subject, where, following injection, the DNA sequences is incapable of recombining with endogenous retroviral sequences and in capable of initiating chronic viral infection in the recipient subject, where the somatic cells are human cells, where the human cells are fibroblasts, myocytes, kidney capsular cells, endothelial cells, epithelial cells of the gut or pituitary cells, where the gene encodes human growth hormone or human insulin, wherein the transfection is by calcium phosphate-mediated transfection, microinjection, electroporation or DEAE-dextran transfection, a regulatable promoter, where the gene is a selectable gene and the promoter is operably linked to the selectable gene, where the selection comprises screening cells in vitro to select a cell possessing desired regulation

properties; and methods of transferring a gene into a recipient subject comprising transfecting somatic cells in vitro with a DNA sequence comprising the gene and a promoter, where the somatic cells are stably transfected, screening resultant cells to select a cells by screening the cells by assaying for mRNA translation of the gene product, cloning and expanding the selected cell to form the10^5 to 10^{10} cells, combining the 10^5 to 10^{10} cells with a physiologically acceptable carrier and inject the cells into a recipient, wherein following injection the DNA sequence is incapable of recombining with endogenous retroviral sequences and the DNA sequence is incapable of causing a chronic viral infection in the recipient subject, where the gene encodes human growth hormone or insulin, where the DNA sequence integrated into the chromosome of the selected cell and where the DNA sequence replicates as an extrachromosomal plasmid.

Claims 135-148 of '200 are drawn to methods producing a therapeutic product in a mammal comprising introducing into a mammal transfected primary or secondary cells comprising an exogenous nucleic acid molecule that comprises or is transcribed into a therapeutic product, the nucleic acid sequence being under control of exogenous nucleic acid sequences, wherein the method also includes culturing the secondary cells to form a clonal cell line, where in said cell a fibroblast, keratinocyte, epithelial cell, endothelial cell, glial cells, neural cells, blood cells, muscle cells or hepatocyte, where the therapeutic product is an enzyme, cytokine, hormone, antigen, antibody, clotting factor, regulatory protein, ribozyme, transcription protein, receptors or antisense nucleic acid molecules.

The present claims and the claims of '200 contain overlapping subject matter for an overlapping and obvious method. The present specification defines the cells to be administered to be a mixture of transfected and non-transfected cells. Therefore, at the time of the instant invention, it would have been obvious to arrive at the claimed methods given methods 135-148 of '200.

Claims 72-78, 82-84 and 104-108 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,303,379. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the elements contained in present claims 72-78, 82-84 and 104-108 are contained within the elements of claims 1-21 in '379.

Present claims 72-78, 82-84 and 104-108 are drawn to a method of transferring a gene into a recipient subject comprising transfecting somatic cells in vitro with a DNA sequence, screening transfected cells to select a cells that is stably transfected with the DNA sequence, cloning and expanding the selected cell in vitro and injected the resulting cell into the recipient subject, where, following injection, the DNA sequences is incapable of recombining with endogenous retroviral sequences and in capable of initiating chronic viral infection in the recipient subject, where the somatic cells are human cells, where the human cells are fibroblasts, myocytes, kidney capsular cells, endothelial cells, epithelial cells of the gut or pituitary cells, where the gene encodes human growth hormone or human insulin, wherein the transfection is by calcium phosphate-mediated transfection, microinjection, electroporation or DEAE-dextran transfection, a regulatable promoter, where the gene is a selectable gene and the promoter is operably linked to the selectable gene, where the selection comprises screening cells in vitro to select a cell possessing desired regulation properties; and methods of transferring a gene into a recipient subject comprising

transfecting somatic cells in vitro with a DNA sequence comprising the gene and a promoter, where the somatic cells are stably transfected, screening resultant cells to select a cells by screening the cells by assaying for mRNA translation of the gene product, cloning and expanding the selected cell to form the10^5 to 10^{10} cells, combining the 10^5 to 10^{10} cells with a physiologically acceptable carrier and inject the cells into a recipient, wherein following injection the DNA sequence is incapable of recombining with endogenous retroviral sequences and the DNA sequence is incapable of causing a chronic viral infection in the recipient subject, where the gene encodes human growth hormone or insulin, where the DNA sequence integrated into the chromosome of the selected cell and where the DNA sequence replicates as an extrachromosomal plasmid.

Claims 1-21 of '379 are drawn to transfected primary or secondary cells comprising an exogenous nucleic acid molecule that comprises or is transcribed into a therapeutic product, where the cell is mammalian or human, where the cell comprises a selectable marker; transfected primary or secondary cells that stably expresses exogenous DNA sequence encoding a therapeutic product, the DNA sequence being under control of DNA sequence of non-retroviral origin, where in said cell a fibroblast, keratinocyte, epithelial cell, endothelial cell, glial cells, neural cells, blood cells, muscle cells or hepatocyte, where the therapeutic product is an enzyme, cytokine, hormone, antigen, antibody, clotting factor, regulatory protein, ribozyme, transcription protein; secondary eukaryotic cells transfected with an exogenous DNA sequence that encodes a therapeutic protein or is itself a therapeutic product, and a DNA sequence of non-retroviral origin that directs expression of the exogenous DNA sequence, where the DNA sequences are episomal, where the cell comprises a DNA sequence encoding a selectable marker, and where the cell is clonal; a heterogeneous cell strain having stably integrated into their genome an exogenous nucleic acid molecule that comprises or is transcribed into a therapeutic product, where the cell is

mammalian or human, where the cell comprises a selectable marker; transfected primary or secondary cells that stably expresses exogenous DNA sequence encoding a therapeutic product, the DNA sequence being under control of DNA sequences of non-retroviral origin, where in said cell a fibroblast, keratinocyte, epithelial cell, endothelial cell, glial cells, neural cells, blood cells, muscle cells or hepatocyte, where the therapeutic product is an enzyme, cytokine, hormone, antigen, antibody, clotting factor, regulatory protein, ribozyme, transcription protein; a heterogeneous cell stain of transfected primary or secondary cells that express exogenous DNA sequences encoding a therapeutic product where the DNA sequence is present episomally.

Each element of the methods in present claims 72-78, 82-84 and 104-108 is found with the cells of claims 1-21 of '379, and the '379 specification defines the cells as to be used in the presently claimed methods. In addition, each element of claims 1-21 of '379 can be found in claims 72-78, 82-84 and 104-108. The present claims require cells that are encompassed by claims 1-21 of '379. Therefore, it would have been obvious to the ordinary artisan at the time of present invention to arrive at the method of the present claims given the cells claimed in '379, and to arrive at the cell of '379 given the method presently claims. Thus, there is two-way obviousness-type double patenting between the present claims and claims 1-21 of '379.

Claims 72-78, 82-84 and 104-108 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,048,729. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010

(Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the elements contained in present claims 72-78, 82-84 and 104-108 are contained within the elements of claims 1-11 in '729.

Present claims 72-78, 82-84 and 104-108 are drawn to a method of transferring a gene into a recipient subject comprising transfecting somatic cells in vitro with a DNA sequence, screening transfected cells to select a cells that is stably transfected with the DNA sequence, cloning and expanding the selected cell in vitro and injected the resulting cell into the recipient subject, where, following injection, the DNA sequences is incapable of recombining with endogenous retroviral sequences and in capable of initiating chronic viral infection in the recipient subject, where the somatic cells are human cells, where the human cells are fibroblasts, myocytes, kidney capsular cells, endothelial cells, epithelial cells of the gut or pituitary cells, where the gene encodes human growth hormone or human insulin, wherein the transfection is by calcium phosphate-mediated transfection, microinjection, electroporation or DEAE-dextran transfection, a regulatable promoter, where the gene is a selectable gene and the promoter is operably linked to the selectable gene, where the selection comprises screening cells in vitro to select a cell possessing desired regulation properties; and methods of transferring a gene into a recipient subject comprising transfecting somatic cells in vitro with a DNA sequence comprising the gene and a promoter, where the somatic cells are stably transfected, screening resultant cells to select a cells by screening the cells by assaying for mRNA translation of the gene product, cloning and expanding the selected cell to form the10^5 to 10^{10} cells, combining the 10^5 to 10^{10} cells with a physiologically acceptable carrier and inject the cells into a recipient, wherein following injection the DNA sequence is incapable of recombining with endogenous retroviral sequences and the DNA sequence is incapable of causing a chronic viral infection in the

recipient subject, where the gene encodes human growth hormone or insulin, where the DNA sequence integrated into the chromosome of the selected cell and where the DNA sequence replicates as an extrachromosomal plasmid.

Claims 1-11 of '729 are drawn to a clonal strain of secondary cells produced fro a transfected primary or secondary cell of primate origin which expresses a therapeutic protein, wherein the cells comprise an exogenous DNA sequence which encodes a therapeutic protein and an exogenous DNA sequence sufficient for expression of the DNA sequence encoding a therapeutic protein, where the secondary cells undergo about 20 or 27 doubling without being immortalized, where the cell is a transfected fibroblast, transfected keratinocyte, transfected epithelial cell, transfected endothelial cell, transfected glial cells, transfected neural cells, transfected blood cells, transfected muscle cells or transfected hepatocytes, where the cells is mammalian or human, where the therapeutic product is an enzyme, cytokine, hormone, antigen, antibody, clotting factor, regulatory protein, ribozyme, transcription protein, where the DNA encodes a selectable marker, and a method of using the clonal strain of secondary cells under conditions suitable for expression of the therapeutic protein.

Each of the elements of present method claims 72-78, 82-84 and 104-108 are encompassed by cell claims 1-11 of '729. For examples, the DNA sequence presently claimed is defined by the present specification as encoding a therapeutic protein, and states the specific proteins claimed in claims 1-11 of '729. The present claims state the cells are cloned, which means secondary cells as claimed in '729. Further, the specification of '729 defines the DNA sequence as being extrachomosomal. Thus at the time of the instant invention, it would have been obvious to the ordinary artisan to reach present claims 72-78, 82-84 and 104-108 given claims 1-11 of '729 and to reach claims 1-11 of '729 given

present claims 72-78, 82-84 and 104-108. Thus two-way obviousness-type double patenting exists between the present claims and claims 1-11 of '729.

Claims 72-78, 82-84 and 104-108 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,054,288. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the elements contained in present claims 72-78, 82-84 and 104-108 are contained within the elements of claims 1-18 in '288.

Present claims 72-78, 82-84 and 104-108 are drawn to a method of transferring a gene into a recipient subject comprising transfecting somatic cells in vitro with a DNA sequence, screening transfected cells to select a cells that is stably transfected with the DNA sequence, cloning and expanding the selected cell in vitro and injected the resulting cell into the recipient subject, where, following injection, the DNA sequences is incapable of recombining with endogenous retroviral sequences and in capable of initiating chronic viral infection in the recipient subject, where the somatic cells are human cells, where the human cells are fibroblasts, myocytes, kidney capsular cells, endothelial cells, epithelial cells of the gut or pituitary cells, where the gene encodes human growth hormone or human insulin, wherein the transfection is by calcium phosphate-mediated transfection, microinjection, electroporation or DEAE-dextran transfection, a regulatable promoter, where the gene is a selectable gene and the promoter is operably linked to the selectable gene, where the

selection comprises screening cells in vitro to select a cell possessing desired regulation properties; and methods of transferring a gene into a recipient subject comprising transfecting somatic cells in vitro with a DNA sequence comprising the gene and a promoter, where the somatic cells are stably transfected, screening resultant cells to select a cells by screening the cells by assaying for mRNA translation of the gene product, cloning and expanding the selected cell to form the10^5 to 10^{10} cells, combining the 10^5 to 10^{10} cells with a physiologically acceptable carrier and inject the cells into a recipient, wherein following injection the DNA sequence is incapable of recombining with endogenous retroviral sequences and the DNA sequence is incapable of causing a chronic viral infection in the recipient subject, where the gene encodes human growth hormone or insulin, where the DNA sequence integrated into the chromosome of the selected cell and where the DNA sequence replicates as an extrachromosomal plasmid.

Claims 1-18 of '288 are drawn to methods of providing a therapeutic product in an effective amount in a mammal comprising transfecting primary cells with a DNA construct comprising exogenous DNA sequences encoding the therapeutic product and DNA sequences sufficient for expression of the exogenous DNA sequence, culturing the transfected primary cell to produce a clonal strain of secondary cells, expanding the clonal cells, and introducing a transfected secondary or a transfected clonal cell into a mammal to product an effective amount of the therapeutic produce, methods of providing a therapeutic product in an effective amount in a mammal comprising culturing primary cells to produce secondary cells, transfect the secondary cells with a DNA construct comprising exogenous DNA sequences encoding the therapeutic product and DNA sequences sufficient for expression of the exogenous DNA sequence, culturing the transfected secondary cells to produce a clonal strain of secondary cells, expanding the clonal cells, and introducing a transfected secondary cell into a mammal to product an effective amount of the therapeutic product

where the primary cells are fibroblasts, keratinocytes, epithelial cells, endothelial cell, glial cells, neural cells, lymphocytes, bone marrow cells or hepatocyte, where the therapeutic product is an enzyme, a cytokine, a hormone, an antigen or a clotting factor, where the DNA sequences sufficient for expression are non-retroviral, and methods of providing a protein to a mammal at biologically significant levels comprising administering secondary transfected mammalian cells which express the protein at physiologically relevant levels, where the protein is an enzyme, a cytokine, a hormone, an antigen or a clotting factor, erythropoietin, human growth hormone or factor VIII.

The present specification defines the terms If claims 72-78, 82-84 and 104-108 as encompassing the elements of claims 1-18 of '288. As an example, while the present claims do not specifically claim the DNA sequence to encode Factor VIII, the specification defines "DNA sequence" as encompassing encoding factor VIII. Further, there is overlap of subject matter in that the claims of '288 state the cells can be fibroblasts and that the DNA sequence encodes a hormone. Certain present claims state the same cell types, and states that the DNA sequence encodes insulin or growth hormone, both are hormones. Thus, it would have been obvious to the ordinary artisan at the time of the instant invention to make the method of present claims 72-78, 82-84 and 104-108 given claims 1-18 of '288. It also would have been obvious at the time of the present invention to make claims 1-18 of '288 given the present claims. Thus there is two-way obviousness-type double patenting between claims 72-78, 82-84 and 104-108 of the present application and claims 1-18 of '288.

It is noted that applicant, with regard to the obviousness-type double patenting rejections, never discussed the merits of these rejections other than to say they traverse. Applicant argues that the previous examiner withdrew obviousness-type double patenting rejections that were of record at that time in an interview summary dated February 7, 2000.

Applicant argues that the present examiner cannot reintroduce the previously withdrawn rejections. Applicant argues that the present examiner must give full faith and credit to the previous examiner. These arguments are not persuasive.

Contrary to applicant's arguments, giving full faith and credit to a previous examiner, does not require a later assigned examiner to permit the continuance of a patenting error. Full faith and credit has been given to the previous examiner but the present examiner believes that two-way obviousness-type double patenting exists. MPEP 704.01 supports the examiner in altering the prosecution of an application if a clear error has been made.

In addition, in reviewing applicant's arguments in the course of prosecution of this application, it appears that a two-way obviousness-type double patenting rejection was never outlined. The examiner has shown that the present claims and those of the cited patents in fact meet the criteria of two-way obviousness-type double patenting. As in early prosecution, the examiner has not relied on a genus-species argument but has shown why the both sets of claims in each rejection encompass one another.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Reynolds, SPE of AU 1632 whose telephone number 703-305-4051. The examiner can normally be reached on M-Th.

Should inquiries be made on or after January 12, 2004, the examiner's phone number will be 571-272-0727. Deborah Reynolds will be reached at 571-272-0734.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 for regular and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

Deborah Crouch

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

December 11, 2003